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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/549,036	04/13/2000	Gregory A Farrell	MST-2322.1	7845

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EXAMINER

HANDY, DWAYNE K

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 03/13/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/549,036**

Applicant(s)  
**Farrell**

Examiner  
**Dwayne K. Handy**

Art Unit  
**1743**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jan 22, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 18-22 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 18-22 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other:

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## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 18-22 are objected to because of the following informalities: In claim 18, line 21, applicant has referred to a “controlling the sheath pump to vary the sample volumetric rate in response...” The Examiner believes this to be an error in the claim. It appears that this is a simple oversight by applicant since earlier in the claim applicant has referred to the sheath stream “flowing at a variable sheath volumetric rate”. Appropriate correction is required.

### ***Inventorship***

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bezanson (Pat. No. 5,106,187) in view of Sklar et al. (5,895,764). Bezanson teaches a method and an apparatus for particle identification. Bezanson's teachings disclose every element of applicant's method except for teaching a sheath fluid which is delivered in laminar flow. Bezanson recites delivering sample and sheath fluid streams (col. 2, lines 11-23), drawing the sample into a suspension stream of fixed diameter (col. 2, lines 13-14), and detecting a characteristic of the sample (col. 2, lines 38-42). Bezanson later recites use of computer to analyze signals and compare the signals to preset limits. The results from the analysis are then used to control the

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operation of the valves and pumps within the system (Figure 3, also col. 3, lines 37-65). As to the limitations of claims 19 and 20, Bezanson discloses detection of particles and particle mixtures in the abstract and invention summary and in claim 2. Finally, Bezanson teaches controlling the pumping rates for optimal characteristic detection (waveform resolution) in column 3, lines 24-28. Sklar et al. discloses a method for controlled sheath flow cytometry. Their method also includes delivering the sample in a suspension stream which includes a sheath flow. Furthermore, the sheath flow is controlled to yield stable laminar flow (col. 3, lines 25-27 and 60-67). Sklar then teaches why they control the sheath flow to yield a laminar flow stream at the top of column 4. Sklar states "When the normal laminar flow is perturbed, some beads will not flow through the optimal laser focus point and will be measured with a reduced fluorescence". It would have been obvious to one of ordinary skill in the art then, to combine the teaching of the use of a laminar sheath flow when using a flow cell in order to insure an accurate reading of the particles flowing through the cell. Both Sklar et al. and Bezanson use flow cells to analyze the particles which are present in the sample. The use of laminar sheath flow would yield better results when combined with the method of Bezanson.

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***Response to Arguments***

6. Applicant's arguments filed 1/22/03 have been fully considered but they are not persuasive. Applicant has amended independent claim 18 to include the limitations of controlling the pumps (sample or sheath) to vary the sample (or sheath) volumetric rate in response to the control parameters at the same time the characteristic is being detected. Applicant has then argued that neither reference taught the feature of controlling the The Examiner disagrees based on passages from the reference Sklar. In columns 3 and 4, Sklar states the following: "A significant difference between the instrument and earlier rapid mix devices is that we *now control sheath as well as sample and reagent delivery*" (column 3, line 60)... "When the normal laminar flow is perturbed, some beads will not flow through the optimal laser focus point and will be measured with a reduced fluorescence. Therefore, *by monitoring fluorescence during the early time points* stable flow can be quantified" (col. 4, lines 15-17).... "We have shortened the time needed to re-establish stable flow by controlling sheath flow. Specifically, we continue to push the mixed sample at higher flow rates for 50 milliseconds after the shunt valve has redirected the flow into the flowcell. To avoid overloading the flow cell's ability to accommodate the large volume, the sheath flow is suspended during that time. After 50 milliseconds, the sample flow is reduced...(col 4., lines 44-50). Taken together, these passages indicate that the sample and sheath flows are indeed controlled during measurement in the flow cell and in response to measuring a characteristic of the flow. Therefore, claims 18-22 are rejected.

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***Conclusion***


7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kubota et al. (5,679,575), Kasdan et al. (6,184,978), Horiuchi (6,317,511), Hansen (6,400,453) teach methods of particle counting which include controlling the feed lines while the particles are being examined in the flow cell.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K. Handy whose telephone number is (703)-305-0211. The examiner can normally be reached on Monday-Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703)-308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703)-772-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0661.

dkh

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700

March 6, 2003